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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,699	01/25/2001	Saul J. Silverstein	61152-A/JPW/AJM/HA	5342

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Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER
LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
1636	10

DATE MAILED: 06/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/769,699	Applicant(s) SILVERSTEIN ET AL.	
	Examiner Gerald Leffers	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, 9 and 11, drawn to compositions and methods comprising the protein 29p for delivery of a desired compound to a eukaryotic cell, classified in class 530, subclass 350; class 435, subclass 7.8.

II. Claim 8, drawn to a monoclonal antibody that binds the 29p protein, classified in class 530, subclass 388.3.

III. Claims 10-11, drawn to methods of expressing and secreting a fusion protein, classified in class 435, subclass 69.7.

IV. Claims 12-17, drawn to pharmaceutical compositions and methods of treating or preventing a disorder in an animal, classified in class 514, subclass 2.

V. Claims 18-23, drawn to a nucleic acid complementary to the sequence encoding 29p and methods of use to detect nucleic acids encoding 29p, classified in class 435, subclass 6; class 536, subclass 23.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I, II, III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as usable together and have different modes of operation, different functions and different effects. The compositions of the different groups

are chemically, structurally and biologically distinct. For example, the compositions and methods of Group I use the protein 29p to deliver a desired compound to a target cell. The monoclonal antibody of Group II binds specifically to the protein 29p. The methods of Group III are drawn towards the distinct process of expressing a fusion protein in eukaryotic cells. The nucleic acid probes and methods of Group V are directed towards detecting a nucleic acid in a sample. The methods of the different groups comprise steps that are not present in or required for the methods of the other groups (e.g. Group 1-delivery of a compound to a cell, Group III-expression of a nucleic acid in a cell, Group V-hybridization of a probe nucleic acid to a target nucleic acid in a sample). Thus, the operation, functions and effects of these different inventions are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

The inventions of Groups I & IV are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The compositions of Group IV comprise therapeutic and prophylactic components that are not necessarily present in or required for the compositions of Group I. The methods of Group IV comprise methods steps that are not required for or present in the methods of Group I (e.g. administration of a therapeutic or prophylactic composition to an animal). The outcomes of the methods of the different groups are different: delivery of a desired compound into a eukaryotic cell (Group I) and therapeutic or prophylactic treatment of an animal (Group II). Thus, the operation, functions and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Inventions of Group IV and Groups II, III & V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as usable together and have different modes of operation, functions and different effects. For example, the monoclonal antibody of Group II binds specifically to 29p. The methods of Group III are drawn towards the process of expressing a fusion protein in eukaryotic cells. The nucleic acid probes and methods of Group V are directed towards detecting a nucleic acid in a sample. None of the inventions of Groups II, III and V comprise or require the compositions and methods of Group IV, which are directed towards the therapeutic or prophylactic treatment of an animal with therapeutic or prophylactic compounds. Therapeutic or prophylactic compounds are not necessarily present in or required for the inventions of the other groups.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G Leffers Jr.
Examiner
Art Unit 1636

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June 4, 2002